

REMARKS

Claims 1-24 were pending. By virtue of this response, claims 25-44 have been added. Accordingly, claims 1-44 are currently under consideration.

Newly-added claims 25-44 are identical to claims 1-20 in co-pending application no. 10/810,185, which was filed as a continuation of the application that is the subject of this response. The claims were added to consolidate the claims of the two pending applications into a single application. No new matter has been added by virtue of these amendments.

Double Patenting

The claims have been rejected as allegedly unpatentable over claims 1-20 of co-pending application no. 10/810,185 under the judicially created doctrine of obviousness-type double patenting. By virtue of this response, claims 1-20 of application no. 10/810,185 have been added to the claims of this application. Applicants intend to allow co-pending application no. 10/810,185 to lapse, which will render the double patenting rejection moot. Applicants request deferral of the double patenting rejection until the co-pending application has lapsed.

Rejection Under 35 U.S.C. §103(a)

Claims 1-24 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over US 5,856,361 (Holt et al.) in view of a data sheet describing uses and properties of capsaicin at www.wholehealthmd.com. Applicants respectfully traverse this rejection.

Rejected claims 1-24 are directed to: (1) kits comprising a first composition comprising capsaicin or a capsaicin analog, and a second composition in which the capsaicin or capsaicin

analog is soluble, or a cleansing gel comprising recited components at recited concentrations and pH; (2) compositions for cleansing a bodily surface comprising recited components at recited concentrations and pH; (3) a method for treating pain comprising administering an afferent nerve fiber blocking regional anesthetic to an affected area, affixing a device comprising a skin adherent patch comprising capsaicin or a capsaicin analog to the affected area, cleansing the area to which the patch has been applied with a composition comprising recited components at recited concentrations and pH, and removing the cleansing composition from the area; and (4) a method for cleansing a bodily surface that has been contacted with an irritating or painful substance, comprising applying a composition comprising recited components at recited concentrations and pH, and removing the composition from the bodily surface. All of these claims include a composition in which capsaicin or a capsaicin analog is soluble or a cleansing composition for removal of capsaicin or another irritating or painful substance from a bodily surface.

Holt et al. do not teach a composition for cleansing or removal of capsaicin or another irritating or painful substance from a bodily surface as claimed. Further, Holt et al. do not teach cleansing compositions with the recited combinations of components at the recited concentrations and pH as presently claimed. Holt et al. teach compositions that contain both capsaicin and an anesthetic substance *in combination*, to provide “a no-burn capsaicin-based pain reliever” (column 2, lines 28-31). The focus of this reference is to provide compositions for delivery of capsaicin into the skin such that the delivery of capsaicin is tolerable to the individual. The compositions taught by Holt et al. do not necessitate removal of capsaicin with a separate cleansing composition, because inclusion of the anesthetic in the capsaicin-containing composition alleviates the skin irritation caused by topical application of capsaicin. In contrast, the presently claimed invention provides cleansing compositions, facilitating *removal* of capsaicin or another irritating or painful substance after application to or contact with a bodily surface. Holt et al. do not provide motivation to develop a composition for removal of capsaicin, because capsaicin is no longer an irritant in the presence of the anesthetic substance in the capsaicin-containing compositions taught in this reference.

A *prima facie* case for obviousness requires, *inter alia*, that there be a suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings of multiple references. MPEP §2142. As discussed above, the Holt et al. reference does not provide motivation to modify the teachings therein or to combine the teachings with another reference to provide a cleansing composition for removal of capsaicin, because the anesthetic provided in the compositions of Holt et al. alleviates the skin irritation caused by application of capsaicin.

A *prima facie* case for obviousness also requires that references, when combined, must teach all of the elements of the claimed invention. MPEP §2142. The Examiner states that “Holt does not specially teach treating first with capsaicin and then washing or neutralizing with a carrier, as claimed.” The cited wholehealthmd website reference does not provide these missing claim elements. The wholehealthmd.com reference describes effects of capsaicin as a skin irritant but does not teach or suggest alleviating these effects by applying a composition in which the capsaicin is soluble for cleansing of a bodily surface to which the capsaicin has been applied. Thus, the combination of the two cited references does not provide all of the elements of the claimed invention as required for an obviousness rejection. Applicants also note that neither of the cited references, nor the combination of the cited references, teaches the solubility characteristics, components, concentrations of components, or pH ranges of the cleansing compositions recited in the claims.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 524522000500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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